

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: ETHICON WAVE 2 CASES	HON. JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' DAUBERT MOTION
FOR KIMBERLY KENTON, MD**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' *Daubert* motion filed against Kimberly Kenton for Ethicon Wave 1, Dkt. 2087 (motion), 2088 (memorandum in support), which Plaintiffs adopted and incorporated by reference for application to the Wave 2 cases identified in their Notice of Adoption, Dkt. 2414. This response applies to those Wave 2 cases identified in Exhibit A to Plaintiffs' Notice of Adoption.¹

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014). Ethicon also hereby adopts and incorporates by reference its Response, Dkt. 2132 (Response) to Plaintiffs' *Daubert* motion filed against Kimberly Kenton, M.D., in Ethicon Wave 1, except that Ethicon adopts and incorporates section A.2 of its previous Response, modified as follows:

¹ Plaintiffs include in their list of cases Plaintiff Phyllis Martin, Case No. 2:12-cv-02029. However, on June 28, 2016, the Court approved the parties' Joint Stipulation of Dismissal with prejudice of this matter, Case No 2:12-cv-02029 Dkt. 29.

- A. **Dr. Kenton is qualified to offer opinions regarding the TVT and TVT-O devices, and her opinions are supported by reliable methodology.**

* * *

2. **Dr. Kenton is qualified to offer opinions regarding the safety of mechanical-cut TVT devices, and such opinions are based on reliable evidence.**

Plaintiffs' argument that Dr. Kenton is not qualified to proffer opinions on the differences, or lack thereof, between mechanical-cut and laser-cut mesh is meritless. As addressed in Ethicon's Response, Dkt. 2132, Dr. Kenton is an experienced surgeon, highly qualified to offer opinions on the clinical data and outcomes regarding the impact of mechanical- and laser-cut mesh when implanted. Dr. Kenton is a fellowship-trained urogynecologist who has a master's degree from the University of Michigan in Clinical Research Design and Statistical Analysis.

Plaintiffs argue that Dr. Kenton bases her opinion on unreliable evidence, attempting to suggest that Dr. Kenton's opinions are based solely on one study comparing TVT-O to a laser-cut device made by another manufacturer. *See* Pltfs' Mem., Dkt. 2088, at 9-10. Plaintiffs mischaracterize Dr. Kenton's testimony and miss her actual opinion completely.

Dr. Kenton does not opine that based upon one study there is evidence that there is no difference between mechanical- and laser-cut mesh. Instead, Dr. Kenton bases her opinion on both (1) her extensive and regular review of clinical literature; as well as (2) outcomes in her own clinical practice. On this sound foundation she opines that the large body of published data fails to show *any* clinically relevant differences between the two – a conclusion supported by her own clinical experience. *See* Expert Report at 6.

In particular, Dr. Kenton has "significant experience with both mechanically and laser cut sling mesh." *Id.* Based on such experience, she states, "Similar to the large body of published

clinical outcomes data – including over 100 RCTs, TVT long-term studies, TVT-O long-term studies, Cochrane Reviews, Registries, Meta-Analyses and Systematic Reviews – I have not found any clinically relevant differences in the design properties or outcomes suggesting clinically significant differences between mechanically cut and laser cut TVT or TVT-O.” *Id.* Dr. Kenton’s experience includes not only general patient data from her high volume practice, but well-documented and tracked data from her design, participation in, and peer-reviewed publications based on extensive clinical studies, including the TOMUS study. *Id.* at 5.

When pressed on whether she tracked outcomes in her own clinical experience based on mechanical- or laser-cut mesh, Dr. Kenton noted that she has not specifically tracked that information. Nor is it necessary that she do so. *See Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *34 (S.D. W. Va. Apr. 24, 2015) (finding that expert’s inability to provide “exact statistics” about the outcome of his patients did not render his personal experience opinions unreliable and that “such detail is not required under *Daubert* to opine as to ‘large-scale safety and efficacy of the Uphold device’”); *Trevino v. Boston Scientific Corp.*, No. 2:13-CV-01617, 2016 WL 1718836, at *33 (S.D. W. Va. May 19, 2016) (same). Relevant here, however, is that she also explained that it would be easy to assess outcomes of mechanical- versus laser-cut in her practice, because she first practiced at one institution using only mechanical-cut TVT and later switched to an institution using only laser-cut, and saw no difference in success rates or complications. *See* Ex. A, Feb. 19, 2016 Deposition of Dr. Kenton (continuation) (“Kenton 2/19/16 Dep.”) at 231:11 – 233:2.² In short, this makes for an easy comparison of outcomes, and Dr. Kenton has seen no differences based on the cut.

² Plaintiffs attach portions of Dr. Kenton’s 2/19/16 deposition to their Motion, Dkt. 2087 (see Exhibit B. For the Court’s convenience Ethicon’s attaches all pages cited in this Response as Exhibit A.

Moreover, Dr. Kenton's opinion is not based solely on observations from her own practice. It is also based on her regular review of medical literature, during which she has seen nothing to suggest "that mechanically cut mesh is inferior or causes complications" or that "laser cut is superior and causes fewer complications." Expert Report at 11. Although she has seen internal Ethicon documents suggesting hypothetical problems, these theories are "not substantiated in the peer-reviewed literature" or in Dr. Kenton's patient retention rates. *Id.* at 12.

"[M]uch of the data" Dr. Kenton relied on in forming her opinions is based on mechanically-cut mesh (Ex. A, Kenton 2/19/16 Dep. at 221:2-4); and she has continually reviewed medical literature and studies since before 2007, when laser-cut mesh became available. She has seen no clinically significant difference in the rates of complications with TVT reported before and after 2007. *Id.* at 419:20 – 420:3.

In her report, Dr. Kenton does cite to one 2006 study comparing laser cut mesh from another manufacturer's product, Obtape, to Ethicon's mechanically-cut TVT-O (Expert Report at 11), but Dr. Kenton is far from relying on this study as her only support for her opinions, as Plaintiffs suggest. As Dr. Kenton explained, she only included this study because it was "the only one that's out there," directly comparing the two meshes. Ex. A, Feb. 19 Depo. at 429:16-19. Indeed, Plaintiffs quote this isolated testimony in their brief (*see* Pltfs' Mem., Dkt. 2088, at 9), but fail to acknowledge Dr. Kenton's additional explanation and detailed analysis of other relevant data.

As further explained by Dr. Kenton, "[t]here are very few data about actually mechanically-cut versus laser-cut, and this is about as good as the data is going to get." *Id.* at 427:7-15. But Dr. Kenton is not saying the lack of data means that she is relying solely on this 2006 study. Rather, Dr. Kenton specifically stated, "I make my decisions not based on a little

itemized study but, rather, on the multitude of the outcome data. . . . There is no data to support that there is a difference [between mechanically- and laser-cut TVT-R], and there is a propensity of data to support the mechanically-cut TVT is safe.” *Id.* at 428:4 – 429:2. Plaintiffs again ignore this relevant testimony.

Plainly Dr. Kenton does not base any opinions on one single study or on an absence of data. Dr. Kenton bases her opinions about mechanical- and laser-cut TVT on a multitude of clinical research and her own extensive experience supporting her opinion that mechanically-cut mesh is safe. None of these present any evidence of clinically relevant differences in the design properties or outcomes suggesting clinically significant differences between mechanically- and laser-cut mesh. Dr. Kenton’s testimony is based on reliable and methods and a variety of data. As such, Plaintiffs’ Motion should be denied.

Respectfully submitted,

ETHICON, INC. AND JOHNSON & JOHNSON

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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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